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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,274	05/18/2001	Sulayman D. Dib-Hajj	044574-5044-US	5193
9629	7590	11/03/2004	EXAMINER	
<b>MORGAN LEWIS &amp; BOCKIUS LLP</b> 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				PAK, MICHAEL D
ART UNIT		PAPER NUMBER		
		1646		

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/856,274	DIB-HAJJ ET AL.
	Examiner Michael Pak	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 July 2004.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 20-44 is/are pending in the application.

4a) Of the above claim(s) 32,33 and 37-39 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 20-31,34-36 and 40-44 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 23 July 2004 has been entered. Claims 20-31, 34-36, and 40-44 are examined below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed 23 July 2004, have been fully considered but they are not found persuasive.

***Claim Rejections - 35 USC § 102***

4. Claims 20-31, 34-36 and 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams (US 5,731,284).

The reason for the rejection has been set forth in the previous office action.

Applicants argue that examiner has provided no basis that patient with injury or degeneration of basal forebrain cholinergic neurons is even experiencing pain nor alleviate pain. Williams teach that GDNF is usefule for the treatment of nerve damage and recites Alzheimer's disease as a cause of nerve damage.(column 5, line 10). Furthermore, Williams teaches that neurotrophic factors are useful for treatming the degeneration of nerve cells and loss of differentiated function that results from many different types of nerve damage including physical injury, damage due to ischemia, neurotoxins, neuropathy

due to chronic metabolic diseases such as diabetes, and neurodegenerative diseases such as Parkinson's, Alzheimer's diseases and Amyotrophic Lateral Sclerosis (column 1, lines 12-33). Williams teach axotomized the rats using a Scuten knife under anesthesia (column 19-20) and treated with GDNF. The axotomy cut both sensory and brain neurons and was painful or the anesthesia would not have been used. The treatment with GDNF inherently alleviate the pain. The GDNF administration inherently affect the sodium channel current flow or expression. The administered GDNF of Williams will inherently affect the dorsal root ganglia or trigeminal neurons which are present in the administered animal or person. The sodium channels in the administered mammal inherently binds the lectin.

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached from 8:30 to 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Michael D. Pak*  
Michael Pak  
Primary Patent Examiner

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